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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,792	10/22/1999	DENNIS T. MANGANO	9114-004-999	2354

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/426,792	MANGANO, DENNIS T.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,13-16,49,51 and 53-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 13-16, 49, 51, 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Request for Continued Examination (RCE) filed October 23, 2003 is acknowledged and accepted. Claims 7-12 are canceled. Claims 49-52 were added on January 7, 2000. Claims 53-55 were added July 5, 2001. Claims 1-6, 13-16, 49, 51 and 53-55 remain under consideration.

A Response to a Restriction Requirement filed July 29, 2004 in which Applicants elected Group I is acknowledged.

The subject matter under consideration remains methods for reducing cardiovascular disease complications following surgery under defined conditions, comprising administering a pharmacologic cardiovascular agent, wherein the agent is a β_1-adrenergic selective blocking agent.

A Declaration under 37 CFR 1.132 of Dennis Mangano filed October 23, 2003 is further acknowledged.

All claims were previously rejected under 35 U.S.C. 103 as being unpatentable over Goldstein et al., J. Cardiovascular Pharmacology, particularly in view of Kataria et al., J. Cardiothoracic Anest.

It was asserted Goldstein teaches the administration of a therapeutic dose of the β_1-selective blocking agent atenolol to patients immediately following cardiac-related surgery. Atenolol decreased both heart rate and blood pressure. No patient with bronchospasm, bradycardia, atrioventricular defects, heart failure or recent myocardial infarction was included. As required by claims 15 and 16, patients suffering from coronary artery disease and those at risk for coronary artery disease were included. Kataria teaches the administration of the administration of the β_1-adrenergic blocking

agent esmolol, intraoperatively and immediately after general surgery, during emergence from anesthesia, to reduce cardiovascular disease complications as tachycardia and/or hypertension.

Applicant argues Goldstein does not teach or suggest treatment prior to, during or immediately after surgery and urges one familiar with the art would have been surprised that therapy for cardiovascular diseases be administered continuously, throughout surgery and the entire hospitalization and after discharge, as well as administration before, during or immediately after surgery and daily thereafter. Applicant further argues Goldstein fails to teach any treatment between surgery and a full two hours after extubation and urges bypass surgery patients were not generally extubated until the following morning after surgery.

Applicant argues Kataria does not teach or suggest any treatment prior to, during or immediately after surgery and daily afterwards and urges one familiar with the art would have been surprised therapy prior to postoperative hypertension would be beneficial.

Applicant states the administration times taught by Goldstein and Kataria are too late following surgery. It is Applicant's position one skilled in the art would have believed administration of a β-blocker prior to during surgery or immediately after surgery and daily thereafter to be contraindicated.

Applicant's arguments have been given careful consideration but are not found persuasive. The administration of the cardiovascular agent, as recited in claims 1, 49 and 53, is "prior to, during surgery **or** immediately after surgery, and daily thereafter".

The claims do not recite continuous administration throughout therapy. The time at which the administration of the cardiovascular agent occurs would reasonably relate to the type of surgery contemplated. The surgery may be any type of operation or a procedure, and all are encompassed in claims 1, 49 and 53. The claims are not restricted to bypass surgery. Daily administration of atenolol may be conventional following certain surgical procedures. The language of the claims does not exclude interruption of all therapy for a 4-hour period before surgery. A contraindication of administration of a β-blocker prior to or during surgery or immediately after surgery and daily thereafter would reasonably relate to the type of surgery contemplated.

Based on the language of the present claims and the absence of unexpected results in non-bypass procedures, the rejection of record is maintained.

No claim is allowed.

The abstracts of Wahr et al, Anesthesiology; Merrick et al., European Journal of Cardio-thoracic Surgery; Davies et al., Anaesthesia and Intensive Care; Lamb et al., European Heart Journal; and Eagle et al., New England Journal of Medicine, are cited to show further the state of the art with respect to the administration of a β-blocker prior to or after surgery.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

October 17, 2004